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Evaluation of Daily Home Spirometry for School Children with Asthma: New Insights

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Summary. Home spirometers are useful for monitoring asthma therapy and for research, but the validity of maneuvers in children is in question. We evaluated the quality of PEF, FEV₁, and FVC data obtained from 67 children with persistent asthma who self-administered spirometry at home using the hand-held ndd EasyOne Frontline Spirometer with full expiratory curve data, electronic measurements of maneuver quality, and on-screen incentives. Half were studied in 2003 in one region, and half in 2004 in another region of Southern California. Subjects were followed at home weekly over 2 months and daily over 10 consecutive days. We retained completed spirometry sessions (9,916) consisting of three of six best maneuvers in the morning, afternoon, and evening. Percent compliance, software assessed repeatability and acceptability modified from American Thoracic Society criteria, and visually assessed quality of maneuvers, were compared across daily and weekly follow-up, study regions, and subject characteristics. Compliance was higher for daily (>90%) than for weekly follow-up (>84%), but not significantly different, and was consistent across subject characteristics. The number with two reproducible and acceptable maneuvers was significantly lower in the first than second region for daily (70 vs. 90%) and weekly follow-up (66 vs. 87%). Of 22,926 software accepted maneuvers, 1,944 (8.5%) were visually rejected (variable effort, cough, glottic closure). Maneuver quality was significantly lower for subjects age 9–12 versus 13–18 years, for subjects not taking anti-inflammatory medications, and for subjects with <80% predicted FEV₁. Longitudinal data collection is possible in children with asthma by employing repeated home training and follow-up, and using spirometers with built in quality assurance and incentive software. Region, age, and multiple indicators of persistent asthma, predict ability to perform reliable and accurate lung function maneuvers. **Pediatr Pulmonol.** 2006; 41:819–828. © 2006 Wiley-Liss, Inc.

Key words: asthma; spirometry; reproducibility of results; patient compliance; data collection; evaluation research.

INTRODUCTION

Spirometry and its variable peak expiratory flow (PEF) have been widely used as an index of measurement for asthma both in the clinical setting and in research trials. The use of PEF can be relatively useful when a skilled technician or medical professional directly guides technique and interpretation. However, the validity of self-administered PEF is questionable. Some previous studies have even shown that it can be less sensitive than a simple symptom diary for revealing acute exacerbations in asthma.^{1,2} In addition, subject compliance and ability to perform maneuvers accurately at home, especially among children is also questionable.^{3,4} Typical home monitoring is done with non-electronic devices. Evidence from three studies proved that around a fourth to a third of non-electronic PEF data was falsified.^{3–5} Despite these and other limitations, daily PEF is still being widely used in clinical asthma trials due to its simplicity and low cost.

The best standard for measurement of pulmonary function has always been the laboratory spirometer and body Plethysmograph. These devices are not used frequently in clinical trials due to expense of use and lack

of portability. Recently more portable hand held devices that have some similar capabilities in measuring lung

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function have become available. These devices have the capability of measuring forced vital capacity (FVC), forced expiratory volume in one second (FEV₁), forced expiratory flow at 25%–75% of FVC (FEF_{25–75}), and PEF. They are superior to peak flow meters by their very ability to measure all of the aforementioned variables as well as compliance because they store their data until retrieved. For the investigator, this mode of data collection in the field could lead to measurements that are more objective and accurate, and include detailed parameters of lung function and maneuver quality checks.

This study aims to evaluate the compliance and technical quality of home spirometry data from school children with asthma, for use in research studies. We obtained home spirometry data from subjects who self-administered spirometry at home using the hand-held ndd EasyOne Frontline Spirometer (nnd Medical Technologies, Chelmsford, MA). Mortimer et al.⁶ previously validated this portable spirometer against an office spirometer (12 L dry rolling seal). They showed a 1.1% difference in FEV₁ and –0.9% difference in FVC. The data and subjects used in the present study are part of a much larger study to evaluate the effects of air pollutants on school children with asthma in Southern California. We report results from 67 subjects who completed 9,916 spirometry sessions, with each session consisting of at least three maneuvers. Each curve was evaluated and measured independently for acceptability by selected criteria. These curves were then further evaluated for visual acceptability by pediatric pulmonology physicians.

MATERIALS AND METHODS

Population and Design

The design of this study involved repeated measures of health outcomes and environmental exposures in children with asthma, and it is referred to as a panel study. We followed 67 school children with asthma in two regions of

Southern California, Riverside City and Whittier. These two regions were specifically chosen due to their high levels of air pollution. Although key to the aims of the overall study, the health impacts of air pollutants measured is beyond the scope of this article. The Institutional Review Boards of the University of California, Irvine approved the study protocol. Informed written consent was obtained from all subjects and one of their legal guardians. Subjects were recruited if they were ages 9–18 years and had an established diagnosis of asthma based on self-reported physician-diagnosed asthma, including at least a 1 year history of episodic symptoms involving wheezing, cough, or dyspnea. The study targeted recruitment of children with mild to moderate persistent asthma based upon a modified severity scale established by the National Heart Lung and Blood Institute.⁷ This included a history in the last 12 months of exacerbations of asthma symptoms requiring the use of prescribed as-needed, oral or inhaled, bronchodilator(s) on 2 or more days per week, regardless of anti-inflammatory medication use. Subjects were also recruited if they were taking oral or inhaled anti-inflammatory medications, regardless of recent symptom frequency. Finally, subjects were recruited with <80% predicted FEV₁ from office spirometry at their baseline visit to the General Clinical Research Center (GCRC), University of California, Irvine. Subjects were ineligible if they smoked or if someone smoked in the subject's home.

Out of 97 eligible subjects evaluated at the GCRC, 13 were unable or unwilling to participate, and did not enter the panel study. Of the 84 who entered, shortly after entry 10 dropped out and 7 were dropped due to non-compliance. Two subjects were dropped later due to non-compliance, but had a sufficient amount of spirometry data for evaluation (66 and 55 sessions) and they were retained for the present analysis of spirometry data quality. Another subject withdrew later in the study and data was retained for the present analysis (59 sessions), leaving 67 subjects.

Prior to entry in the panel study, subjects were administered a background questionnaire. For 67 subjects in the panel study, responses showed 5 subjects (7.5%) reported having been admitted to the hospital in the past 12 months, and 17 subjects (25%) had been seen in the emergency room at least once in the past 12 months for their asthma. In addition, 22 subjects (33%) reported the need for inhaled bronchodilators (IBD) multiple times per week, 9 subjects (13%) required IBD at least weekly, and 35 subjects (52%) required IBD less frequently or could not recall usage frequency. Only 11 subjects (17%) reported not having used some form of inhaled corticosteroid as a controller medication for their asthma in the last year. Seven of these subjects did not frequently use IBD either, but five of them had percent predicted FEV₁ <80%, and the other two had several recent asthma exacerbations requiring physician evaluations.

ABBREVIATIONS

ATS	American Thoracic Society
BEV	Back-extrapolated volume
dFEV ₁	Difference between highest and 2nd highest FEV ₁ within in a test session
dFVC	Difference between highest and 2nd highest FVC from an acceptable effort
dPEF	Difference between highest and 2nd highest PEF from an acceptable effort
EOTV	End-of-test volume
FEF _{25–75}	Forced expiratory flow between 25% and 75% of FVC
FET	Forced expiratory time
FEV ₁	Forced expiratory volume in one second
FVC	Forced vital capacity
GCRC	General Clinical Research Center
IBD	Inhaled bronchodilators
PEF	Peak expiratory flow
PEFT	Time to peak expiratory flow

The first site of study was Riverside where two groups of approximately 16 asthmatics each were followed in alternating 1-month blocks over a 4-month period in the late summer through late fall of 2003 with daily measures of health outcomes from each subject. This was repeated at a second site in the late summer through late fall 2004 in Whittier. This time of the year was chosen because of historically high levels of particulate air pollution in the Los Angeles basin.

Subjects performed forced expiratory flow maneuvers first on an office spirometer during their baseline visit to the GCRC. Then, subjects were trained in home on how to perform expiratory flow maneuvers with the ndd portable spirometer during a 5-day run-in period (around an hour on the first day, then around 15–30 min per day for the next 4 days as needed). That data is not included in the present analysis. Subjects were instructed to perform spirometry in the morning, afternoon, and evening, and to complete an electronic diary every two waking hours reporting health outcomes, asthma medications, and time place activity information.

Subjects were followed in two blocks of 1 month each for a total of 56 days when they performed thrice-daily spirometry and completed the diary. Subjects further participated in a more intensive phase of study over a continuous 10-day period within one of each subject's 2 months of follow-up. This additionally involved wearing a personal air sampler to measure exposure to air pollutants, and providing a daily measurement of exhaled nitric oxide. Generally, four subjects were followed in each 10-day period and on-site validity checks were conducted daily in their homes. During days when subjects were not wearing the personal air sampler (approximately 46 days) they were followed once each week at their home for validity checks to ensure compliance. Four of the 67 total subjects did not participate in the 10-day exposure assessment and their data are only included in the analysis of spirometry data from the weekly follow-up.

Spirometry Methods and Assessment of Repeatability and Acceptability

The ndd portable spirometer is a small hand held device that uses an ultrasonic flow sensor to measure air flow, thus eliminating many problems with other techniques because measurements are independent of temperature, humidity, pressure, and gas composition. It further uses ndd's disposable mouthpiece, spirette™, with no sensor elements and thus does not contribute or affect air flow measurement. It has a large memory capacity (700 sessions). A graphic display of 64 × 160 pixels along with a 14-button rubber keypad allow for subject visualization of maneuver performance messages and input of data (see below).

The ndd portable spirometer has software that complies with American Thoracic Society (ATS) criteria for acceptability and repeatability.^{8,9} Acceptability parameters are standardized measurements of the technical quality of a maneuver. Repeatability is a measure of the repeatability of expiratory parameters from one maneuver to the next, and is measured by the differences between the highest and second-highest FVC, FEV₁, and PEF (dFVC, dFEV₁, dPEF). Because studies have shown that the ATS criteria,⁹ designed primarily for adults, can be difficult for children to achieve,^{8,10} we modified ATS criteria for children with asthma (Table 2).^{6,8,10} We lowered the ATS⁹ recommended forced expiratory time (FET) from 6 to 4 sec given the findings of Arets et al.,⁸ who found only 15% of children with obstructive lung disease who were experienced in spirometry were able to achieve FET >6 sec for otherwise acceptable maneuvers, similar to the findings of Desmond et al. in children with obstructive lung disease (19%).¹⁰ Enright et al.¹¹ found a majority of a general population sample of children achieved FET >6 sec (65%). We also focused evaluation on premature termination of effort or abrupt ending based on the end-of-test volume (EOTV) (Table 2). To assess accurately EOTV and thus abrupt ending, we calculated FET and EOTV to end of the expiratory plateau and did not include negative (inspiratory) flow. The end of test was marked by NDD software where inspiration >150 ml occurred or a plateau was detected (volume change <45 ml over 2 s for FET <4 s or 60 ml for FET ≥4 s). We also considered the fact that children with asthma show considerable variability in pulmonary function due in part to bronchial reactivity. Further, ATS criteria are intended for in-clinic spirometry guided by technicians using a laboratory spirometer. Therefore, we used a more relaxed goal for repeatability than that recommended by the ATS,⁹ by setting FEV₁ and FVC repeatability at 10% instead of 5%, and PEF at 20% instead of 10%. Because the curves were also visually evaluated, we were able to reject unacceptable curves that met less stringent repeatability criteria. When almost the entire second best curve was “smooth” and perfectly acceptable, but a small portion of the curve showed “a departure,” it was reasonable to accept rather than reject the test session. We visually determined variable effort and other quality problems where there was more than around a 10% deviation from the expected smoothed curve. Maneuver sessions that met acceptability and repeatability criteria by the software were independently reviewed by physicians trained in pediatric pulmonology. Physicians classified each maneuver rejected based on the reasons for rejection (cough, glottic closure, variable effort, or a combination of errors). Figure 1 gives examples. Quality problems were defined by reference to available standardized flow-volume curves showing established abnormal or disrupted curves.

Acceptability and repeatability criteria were custom programmed into the software for this study by ndd technicians. The ndd EasyOne Frontline model stores raw data for all three best maneuvers in memory. We developed custom SAS (Cary, NC) programs (available upon request) to output performance variables and plot three best curves for analysis and improved visual review over the ndd printout of the single best curve.

Specific protocols and instructions were given to all technicians doing field training and follow-up. Each spirometer was checked for calibration ($\pm 3\%$) with a 3 L syringe according to the manufacturer's specifications before the start of each 1-month follow-up and before each 10-day follow-up. Subjects were instructed to use nose clips. The software programming on the ndd portable spirometer automatically stopped after three

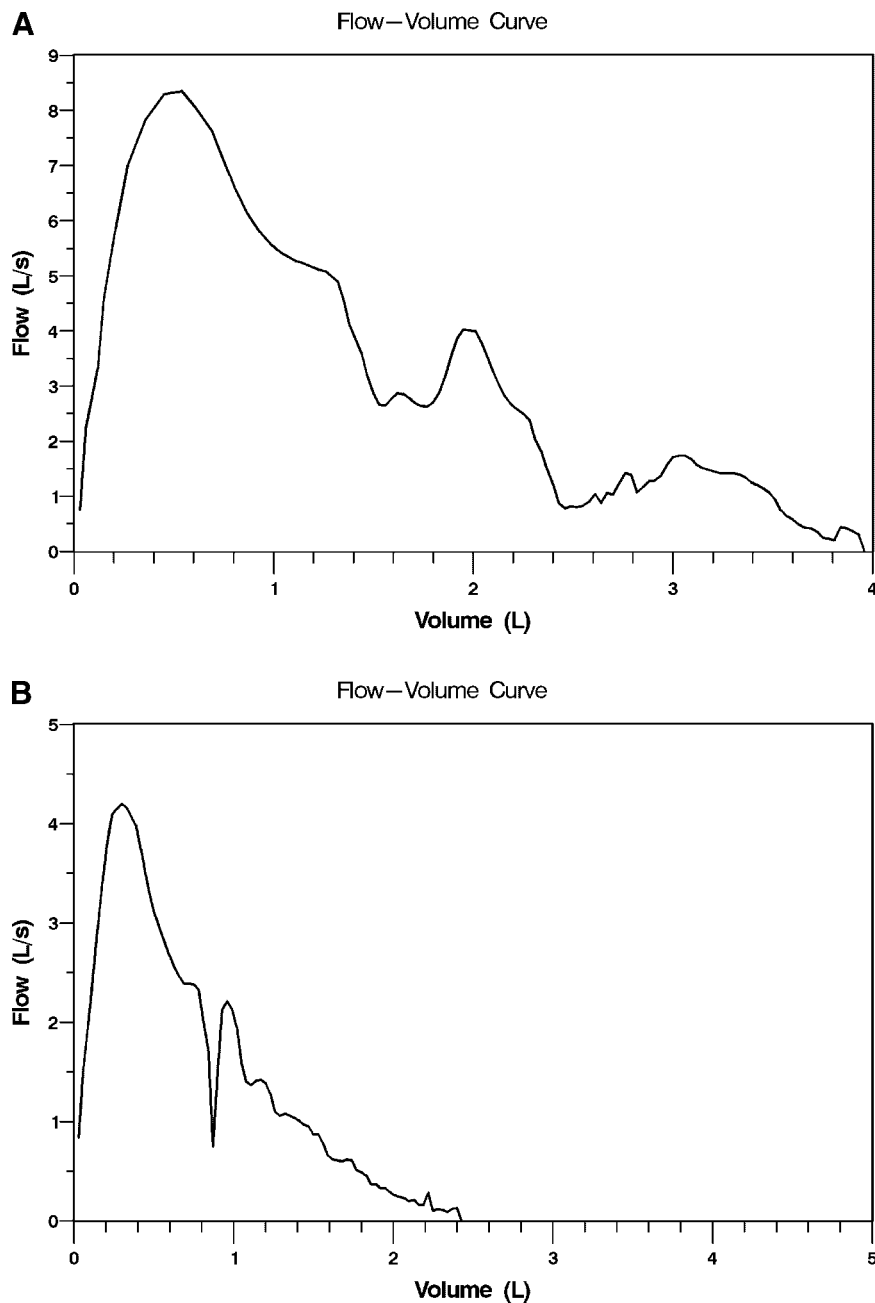


Fig. 1. Examples of curves with visual scoring errors. **A:** Variable effort: intermittent deceleration and acceleration in flow, which may also be intermittent breaths during expiratory flow maneuver; **(B)** Glottic Closure: abrupt interruption in expiratory flow causing a sharp spike downward indicating an abrupt stop and start in flow; **(C)** Cough: erratic interruption in expiratory flow, along with repetitive glottic closures.

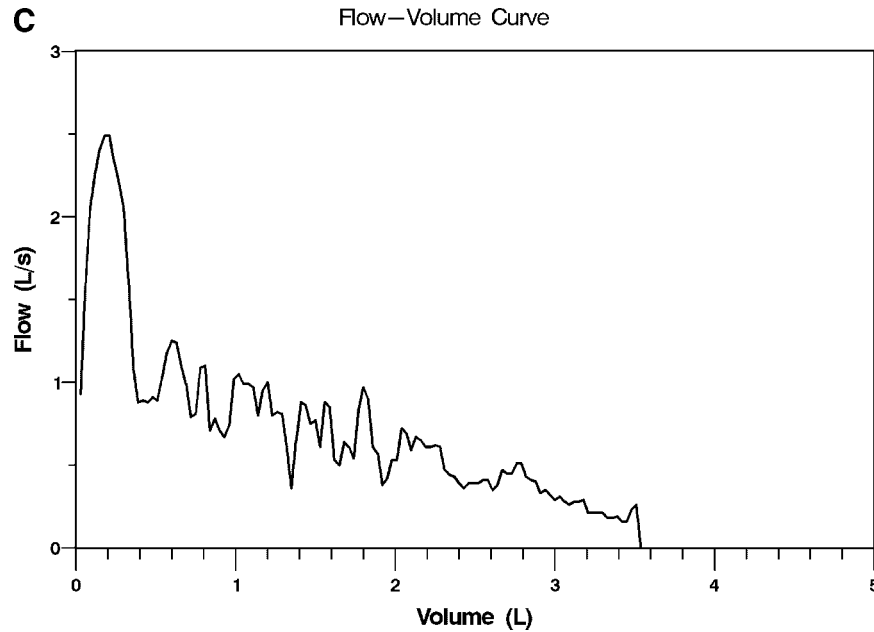


Fig. 1. (Continued)

good maneuvers were obtained, but would give each participant up to six chances to meet acceptability and repeatability criteria (Table 2). If the participant were unable to meet repeatability and acceptability criteria after six attempts, the spirometer would automatically store the best three attempts based on calculation of the largest $FEV_1 + FVC$. The spirometer also gave intermittent instructions to subjects to aid them in performing acceptable and reproducible maneuvers based on the error of each attempt (Table 2). To unmask the effects of air pollutants, it was emphasized to all subjects the importance of doing sessions prior to the use of an IBD unless necessary and to wait at least 4 hr after the use of an IBD before performing a session. Furthermore, subjects were required to answer yes/no questions generated by the spirometer after each spirometry session [(1) Did you have any cough during this test? (2) Did you need to use your rescue medication in the last hour?]. Answers specific to each spirometry session were stored in memory.

Subjects received a handbook that contained detailed instructions on use of their spirometer and in the appropriate technique for doing spirometry sessions. In addition, a large and laminated one-sheet guide with stepwise illustrations was given to subjects and placed in a prominent place in the home where maneuvers were done. They were encouraged to refer to the handbook and one-sheet guide if needed. During follow-up, research technicians downloaded data into laptops during home visits and checked compliance with the three daily sessions, and the acceptability of maneuvers as generated by the ndd software (v 2.6). Subjects were retrained as needed. The data manager using our custom SAS

programs checked data again the next morning. Problems were reported to field staff and subjects were retrained if needed that daily follow-up or before the next weekly follow-up. Compliance was further encouraged by audio reminder alarms on the ndd portable spirometer, and by a monetary sliding scale based on the number of maneuvers performed with each session. Subjects performing most of the maneuvers (17–21 per week) received a bonus payment as well. The ndd software also awarded 500 points for sessions with three acceptable and two reproducible maneuvers, but only 200 points if all six attempts failed acceptability and repeatability criteria. This was used as an additional behavioral incentive.

Analysis

We compared the percentage compliance, and repeatability and acceptability of maneuvers between daily and weekly follow-up, between study regions (Riverside vs. Whittier), and across key subject characteristics to better understand the underlying determinants of data quality. Key subject characteristics included gender, use of controller medications, age group (9–12 vs. 13–18 years old) and percent predicted $FEV_1 < 80$ versus $\geq 80\%$ based on repeated measurements of acceptable and reproducible maneuvers. Percent-predicted normal FEV_1 were calculated for a given height, age, gender, and race-ethnicity using normal lung function equations from the National Health and Nutrition Examination Survey III.¹² Tests for significant differences in data quality were performed across these binary group characteristics using a two-sided

TABLE 1—Study Group Characteristics

Subject variables	Data
Subject number	
Riverside	33
Whittier	34
Age, mean (range)	13.5 (9–18 years)
Gender N (%)	
Female	25 (37.3)
Male	42 (62.7)
Race N (%)	
White	25 (37.3)
Black	15 (22.4)
Hispanic	24 (35.8)
Asian	3 (4.5)
Mean percent predicted FEV ₁ (SD)	
Riverside	80.8 (16.3)
Whittier	89.5 (12.7)*

* $P < 0.05$ for difference between Riverside and Whittier in percent predicted FEV₁.

t-test with Satterthwaite's method in SAS v 9.1 Proc TTEST.¹³

RESULTS

The 67 subjects in this repeated measures study were of diverse racial and ethnic background, and ranged in age from 9 to 18 years (mean 13.5 years) (Table 1). There were more males than females. Mean percent-predicted FEV₁ from all valid maneuvers during daily home follow-up was lower for subjects in Riverside compared with Whittier (80.8% vs. 89.5%, respectively).

Despite the prolonged period of study, all home spirometers assigned to subjects for the duration of this study were returned undamaged. One spirometer was found to have minimal loss of calibration (4%) after 4 weeks of use and was sent back to the manufacturer for calibration.

The distribution of performance variables is shown in Table 3. Evaluation of acceptability and repeatability of maneuvers is shown in Table 4. Daily versus weekly follow-up values of acceptability and repeatability did not differ significantly, although there was a consistent trend of higher values during daily follow-up. There was no statistically significant difference between the more strict criteria of three acceptable, two reproducible maneuvers versus two acceptable and reproducible maneuvers, hereafter referred to as criteria A and B, respectively. As expected, the lowest percentage of acceptability and repeatability occurred when all three flow-volume criteria were evaluated simultaneously, but values remained >75% across all parameters.

Table 5 shows the frequency of subject errors detected by ndd EasyOne software, which labeled the spirometry curves as unacceptable. The most common error made by subjects was abrupt ending and invalid time to peak expiratory flow (PEFT).

Table 6 shows causes of physician visual rejection of software accepted maneuvers. Variable effort was the most common cause of rejection, often in combination with cough and glottic closure. Glottic closure followed by cough was the next most common. Overall frequency of causes for visual rejection was small being 10.4% and 8% of overall acceptable and reproducible maneuvers for daily and weekly follow-up, respectively.

Evaluation of compliance showed excellent overall compliance of >90% for daily follow-up and >84% for weekly follow-up data (Table 7). This finding remained consistent across study region and subject characteristics. However, the quality of maneuvers differed across a number of factors. Subjects in Riverside performed worse than subjects in Whittier for all comparisons. There were also significant differences across subject characteristics for both daily and weekly follow-up data for criteria A and B, and for visually acceptable criteria test sessions. These

TABLE 2—Acceptability and Reproducibility Criteria

Acceptability criteria	Instruction to subjects if criterion not met
Back-extrapolated volume (BEV) must be <150 ml or 5% of the FVC	Do not hesitate at the beginning of the maneuver
Time to peak expiratory flow (PEFT) must be >40 msec and ≤160 msec ^a	Blast out faster when starting the maneuver
a. We later added an additional instruction in the second half of study for maneuvers where PEFT was ≤40 msec: "wait until buzz before blowing out."	
No abrupt ending, which is when EOTV >100 ml is accumulated in the last 0.5 sec before the end of test or for age <12 year, 50 ml in the last 0.25 sec before the end of test. EOTV is calculated from the forced expiratory time (FET) (0.5 or 0.25 sec to end of expiration). Abrupt ending also occurs if FET is <2 sec [end-of-test volume (EOTV)]	Blow out longer
Repeatability Criteria	
Difference between the highest PEF and 2nd highest PEF (dPEF) within in a test session must be within 20%	Blast out harder when starting the maneuver
Difference between the highest FEV ₁ and 2nd highest FEV ₁ (dFEV ₁) within in a test session must be within 10%	Take a deeper breath
Difference between the highest FVC and 2nd highest FVC (dFVC) within in a test session must be within 10%	Take a deeper breath

TABLE 3—Distribution of Variables for the Quality of the Best Maneuver¹

	Percentiles						
	5th	10th	25th	50th	75th	90th	95th
BEV (ml)	18.1	26.9	42.5	62.5	86.3	114.4	133.7
BEV (% FVC)	0.7	1.0	1.5	2.1	2.8	3.6	4.1
PEFT (msec)	50.0	60.0	60.0	80.0	100.0	120.0	140.0
EOTV (ml)	2.5	3.8	6.9	12.5	24.4	42.5	55.6
FET (sec)	2.5	2.8	3.4	4.6	6.2	8.4	10.0
dFVC (%)	0.3	0.6	1.4	3.4	7.0	14.0	24.8
dFEV1 (%)	0.3	0.6	1.6	3.7	7.5	15.5	26.9
dPEF (%)	0.5	1.1	2.7	6.2	12.4	25.2	38.9

¹The maneuver with the highest FEV₁ + FVC for each of 9,916 spirometry sessions.

characteristics included age group 9–12 years performing worse than 13–18 years, and subjects with FEV₁ ≥80% predicted performing significantly better than their counterparts. Subjects not on controller medications performed worse than those taking them, but this difference was statistically significant only for daily follow-up. Performance between daily and weekly follow-up was not significantly different. Weekly follow-up performance between months one and two of subject follow-up was not significantly different.

DISCUSSION

Overview of Findings and Comparison with the Literature

Mortimer et al.,⁶ evaluated data from asthmatic children using the ndd portable spirometer, which had quality control software with modified ATS acceptability and repeatability criteria similar to the present study, including the relaxed goal for repeatability and end-of-test criteria tailored for asthmatic children. They conducted an asthma panel study of 92 children with asthma and found overall compliance was 87% for 2 weeks (2,151 sessions), similar to our compliance for weekly follow-up over 2 months

(85%–90%). They also found the proportion of sessions with at least two acceptable and reproducible maneuvers by software criteria was 62% overall, which is lower than the present study (76%–80%). However, their study differs from the present in that subjects were younger (ages 6–11), and no exclusion of training period data was reported.

We found a non-significant small increase in the quality of the maneuvers from month 1 to 2, and no change in compliance. Wensley and Silverman¹⁴ analyzed the quality of data and compliance in 90 asthmatic school children ages 7–14 years who used a Vitalograph home spirometer and were followed at home monthly over 4 months. They found some deterioration of collected data over time primarily due to decreasing compliance (from 81% to 70%) rather than any deterioration in maneuver quality (from 82% to 80%). However, quality could be only assessed by percent variability of FVC + FEV₁ for the two best maneuvers.

We previously used the Vitalograph 2110 (Vitalograph, Inc., Lenexa, KS) in a panel study of 19 children with asthma each followed daily for 14 days, and found 80% compliance and 81% of sessions had acceptable and reproducible FEV₁ data.¹⁵ Although these results are roughly comparable to the present study, quality assurance

TABLE 4—Acceptability and Repeatability of Self-Administered Spirometry for Daily Compared with Weekly Staff Follow-Up*

Parameters	At least three acceptable, two reproducible maneuvers		At least two acceptable, two reproducible maneuvers	
	Daily follow-up	Weekly follow-up	Daily follow-up	Weekly follow-up
FEV ₁ , FVC, PEF	78.7 ¹	75.2	79.9	76.4
FEV ₁ only	85.6	82.0	87.1	84.0
FVC only	84.6	81.4	86.3	83.6
PEF only	89.2	85.4	91.2	87.8
Total no. of spirometry sessions	1814	8102	1814	8102

*There were no *P* < 0.05 differences between frequencies for daily versus weekly follow-up or between three acceptable, two reproducible maneuvers versus two acceptable, two reproducible maneuvers.

¹Percent of total spirometry sessions collected (three maneuvers per session).

TABLE 5—Frequency of Maneuver Errors

Error type ¹	Best maneuver ² no. (% total)	2nd best maneuver no. (% total)	3rd best maneuver no. (% total)
Abrupt ending	32 (0.32)	76 (0.77)	170 (1.71)
PEFT	18 (0.18)	79 (0.80)	209 (2.11)
PEFT + abrupt ending	3 (0.03)	20 (0.20)	32 (0.32)
BEV	10 (0.10)	26 (0.26)	73 (0.74)
BEV + abrupt ending	2 (0.02)	6 (0.06)	9 (0.09)
BEV + PEFT	14 (0.14)	42 (0.42)	111 (1.12)
BEV + PEFT + abrupt ending	1 (0.01)	8 (0.08)	15 (0.15)
Total maneuvers	9916	9916	9916

¹See Table 2 for definitions.

²Maneuvers are ranked in order of best effort (FEV₁ + FVC).

software was limited to PEFT (acceptable at 40–290 msec) and prompting of subject maneuvers until PEF readings were within 10%.

Given that subjects in the present study were usually not coached by technicians, the distribution of performance variables shows the quality of the data is reasonably good (Table 3). Enright et al.¹¹ assessed the quality of technician-administered spirometry done annually for 3 years in a large cohort study of over 4,000 Southern California school children ages 9–18. The distribution of our PEFT and Back-extrapolated volume (BEV) variables in Table 3 are similar to theirs. We show no negative EOTV in the lower distribution as they did (see Materials and Methods), but our 95th percentile was only 56 ml. The FET in the general population sample of Enright et al.¹¹ was longer (median 6.6 s) compared with a median of 4.6 sec for the persistent asthmatics of our study. Our repeatability results were worse. The median dFEV₁ in Enright et al.¹¹ was 1.2% whereas ours was 3.7%. Further evaluation of the quality of maneuvers in our study was made by evaluating the visual acceptability of curves that met software criteria for at least two acceptable and two

reproducible curves. Variable effort was the most frequent cause of visual rejection (Table 6).

In the present study, we found that both compliance and quality of curves were higher for subjects followed up daily as compared with weekly (Tables 4 and 7), but differences were not statistically significant. This consistency in technique and compliance could be attributed to the spirometer itself, which as mentioned above, contains inherent quality assurance measures that do not require the presence of a field team member to correct subjects on common errors during maneuver attempts (Table 2). Subjects were also given a manual and a small poster size colored pictograph describing and depicting a subject doing appropriate spirometry technique. In addition, compliance was regularly encouraged by monetary incentives, an on-screen point system, and audio alarms in the ndd software to remind subjects during selected periods (see Materials and Methods).

We found quality of maneuvers was significantly worse in younger subjects. This age difference in the quality of home spirometry was also found by Mortimer et al.,⁶ Enright et al.,¹¹ and Pelkonen et al.¹⁶ Multiple indicators of persistent asthma also predicted ability to perform reliable and accurate lung function maneuvers as shown by significantly better maneuver quality among subjects with $\geq 80\%$ predicted FEV₁ and subjects on controller medication. We speculate that the improved performance with better lung function is due to the intrinsic nature of the subjects' lung disease (asthma). There were no significant differences in the distribution of controller medication use by percent predicted FEV₁.

The quality of maneuvers was also significantly worse in Riverside as compared with Whittier. Underlying group characteristics might explain this. Riverside and Whittier were significantly different in the number with $< 80\%$ predicted FEV₁ (42% vs. 18%, respectively, Fisher's exact $P < 0.05$). However, the regional groups were similar in use of maintenance asthma controller medications (64 vs. 68%). The groups did differ by age sub-group with the Riverside group having more subjects 9–12 years old than the Whittier group (48.5% vs. 17.7%). However, there was

TABLE 6—Causes of Visual Rejection of Maneuvers That Met Acceptability Criteria

Causes of visual rejection	Daily follow-up	Weekly follow-up
Cough	45 (1.0) ¹	152 (0.8)
Glottic closure ²	33 (0.7)	223 (1.2)
Variable effort	262 (6.0)	724 (3.93)
Cough/variable effort	65 (1.5)	71 (0.4)
Cough/glottic closure	9 (0.2)	71 (0.4)
Cough/glottic closure/ variable effort	9 (0.2)	14 (0.1)
Glottic closure/ variable effort	31 (0.7)	240 (1.3)
Total rejected	454 (10.4)	1496 (8.0)
Total acceptable	4350 (100)	18576 (100)

¹Number rejected (percent of total acceptable maneuvers for the follow-up frequency).

²Includes problems at the end of the curve, which may not have had an effect on FEV₁ or FVC.

TABLE 7—Compliance, Acceptability and Repeatability of Self-Administered Spirometry: Differences by Panel, Age, Controller Medication Use and Lung Function

Daily Follow-up					
Characteristic	No. of Subjects	Compliance: No. test sessions collected (% expected)	Percent ¹ with 3 acceptable, 2 reproducible	Percent with 2 acceptable and 2 reproducible	Percent visually acceptable with 2 acceptable and 2 reproducible
Riverside	31	881 (92.8)	68.8 ²	69.7 ²	54.9 ²
Whittier	32	933 (95.2)	88.1	89.6	81.7
Age group					
9–12	21	607 (95.0)	66.7 ²	67.9 ²	56.5 ²
13–18	42	1207 (93.6)	84.8	86.0	74.8
Controller medication					
On	42	1232 (94.6)	83.8 ²	84.8 ²	72.3
Not on	21	582 (92.8)	68.0	69.6	61.0
Mean percent predicted FEV ₁					
≥80	45	1289 (93.6)	82.9 ²	84.6 ²	73.7 ²
<80	18	525 (95.1)	68.4	68.6	56.4
			Weekly follow-up		
Riverside	33	3918 (84.8)	64.7 ²	65.5 ²	52.0 ²
Whittier	34	4184 (89.7)	85.0	86.6	78.4
Age Group					
9–12	21	2801 (87.4)	64.6 ²	65.7 ²	54.4 ²
13–18	42	5301 (87.2)	80.8	82.1	71.5
Controller Medication					
On	42	5288 (87.4)	78.0	79.5	66.9
Not on	21	2814 (87.0)	69.9	70.6	63.1
Mean percent predicted FEV ₁					
≥80	45	5576 (87.2)	81.5 ²	82.7 ²	74.3 ²
<80	18	2526 (87.5)	61.2	62.6	46.4
Follow-up					
Month 1	67	4210 (87.8)	72.7	73.8	64.0
Month 2	62	3892 (86.7)	77.8	79.3	67.3

¹Percentages are the number with the stated characteristic divided by the number of spirometry sessions collected.

²*P* < 0.05 *t*-test with Satterthwaite’s method for differences in performance between region, age, controller medication group, percent predicted FEV₁, and month of follow-up.

no difference in maneuver quality by age sub-group in Whittier, and performance was a significantly better in Whittier for both 9–12 and 13–18 year old subjects (not shown). We speculate that unmeasured characteristics led to this regional difference in quality of maneuvers.

Application of Findings to Research

In field studies of chronic lung diseases that require frequent measurements of pulmonary function, the use of peak flows has been one of the most common measurements available to investigators.² This is largely due to the ease of use of peak flow meters, portability and low cost. Unfortunately, measurement of peak flows has been shown to have many disadvantages for use in research or clinical management of patients with asthma or other chronic lung diseases.^{1–5,17–20} Previously, full measurement of pulmonary function that allows for evaluation of other critical variables of air flow (FEV₁, FVC, FEF_{25–75}) has been limited only to the office or laboratory, thus precluding repeated daily measurements.

Portable spirometers such as the one used in this study demonstrate several advantages over peak flow meters. First, its ability to generate true flow-volume loops not only allows for evaluation of various parameters of expiratory flows (FEV₁, FVC, FEF_{25–75}, PEF), but also allows for evaluation of technique and effort based on professional standards programmed into the software (Table 2). The measurement of these parameters allows for evaluation of both central and peripheral airway function, thus the potential for better and more expansive evaluation of clinical status. Finally, quality assurance is enhanced by the machine’s ability to: (1) give subjects correcting instructions on the next maneuver attempt based on errors evaluated on the current maneuver attempt; and (2) store large volumes of time-date-stamped data.

CONCLUSIONS

Although there were subgroup differences in compliance and maneuver quality in this study, overall performance with the use of the ndd portable spirometer

was good, with acceptability and repeatability criteria being met at its most stringent (three acceptable and two reproducible maneuvers) more than 61% of the time for all subgroups. The lack of significant differences in quality of maneuvers and compliance for daily versus weekly follow-up supports the effectiveness of quality assurance measures built into the ndd and the ease of performing maneuvers for well-trained subjects even as young as age 9 years.

The use of portable spirometers with the specifications described is feasible and results in a high yield of valid data for field research. Handheld spirometers with capabilities such as the ndd EasyOne are superior to simple peak flow meters in allowing for comprehensive measures of lung function, quality assurance measures, compliance markers, and ease of use. This allows researchers to evaluate the impact of clinical interventions or environmental exposures on chronic lung diseases such as asthma.

We found data quality was affected by a variety of influences, including clinical severity, treatment regimen, and population differences, all of which should be taken into account when interpreting data. Despite these impacts on data quality, results of this large panel study of pediatric asthma show that durable and portable spirometers offer quality assurance and longitudinal data collection capabilities. Further studies evaluating portable electronic spirometry in research and clinical settings are strongly encouraged.

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REFERENCES

1. Chan-Yeung M, Chang JH, Manfreda J, Ferguson A., Becker A. Changes in peak flow, symptom score, and the use of medications during acute exacerbations of asthma. *Am J Respir Crit Care Med* 1996;154:889–893.

2. Mortimer KM, Redline S, Kattan M, Wright EC, Keresmar CM. Are peak flow and symptom measures good predictors of asthma hospitalizations and unscheduled visits? *Pediatr Pulmonol* 2001;31:190–197.
3. Redline S, Wright EC, Kattan M, Keresmar C, Weiss K. Short-term compliance with peak flow monitoring: results from a study of inner city children with asthma. *Pediatr Pulmonol* 1996;21:203–210.
4. Verschelden P, Cartier A, L'Archeveque J, Trudeau C, Malo JL. Compliance with and accuracy of daily self-assessment of peak expiratory flows (PEF) in asthmatic subjects over a three month period. *Eur Respir J* 1996;9:880–885.
5. Kamps AW, Roorda RJ, Brand PL. Peak flow diaries in childhood asthma are unreliable. *Thorax* 2001;56:180–182.
6. Mortimer KM, Fallot A, Balmes JR, Tager IB. Evaluating the use of a portable spirometer in a study of pediatric asthma. *Chest* 2003;123:1899–1907.
7. National Heart, Lung, and Blood Institute (NHLBI). The expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma. Bethesda MD: NHLBI, National Institutes of Health. Pub no 97-4051, 1997.
8. Arets HG, Brackel HJ, van der Ent CK. Forced expiratory maneuvers in children: do they meet ATS and ERS criteria for spirometry? *Eur Respir J* 2001;18:655–660.
9. American Thoracic Society. Standardization of spirometry 1994 update. *Am J Respir Crit Care Med* 1995;152:1107–1136.
10. Desmond KJ, Allen PD, Demizio DL, Kovesi T, Coates AL. Redefining end of test (EOT) criteria for pulmonary function testing in children. *Am J Respir Crit Care Med* 1997;156:542–545.
11. Enright PL, Linn WS, Avol EL, Margolis HG, Gong H, Jr., Peters JM. Quality of spirometry test performance in children and adolescents: experience in a large field study. *Chest* 2000;118:665–671.
12. Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. *Am J Respir Crit Care Med* 1999;159:179–187.
13. SAS Institute Inc. SAS/STAT[®] 9.1 User's Guide. Cary, NC: SAS Institute Inc., 2004; pp 4775–4794.
14. Wensley DC, Silverman M. The quality of home spirometry in school children with asthma. *Thorax* 2001;56:183–185.
15. Delfino RJ, Quintana PJE, Floro J, Gastañaga VM, Samimi BS, Kleinman MT, Liu L-JS, Bufalino C, Wu C-F, McLaren CE. Association of FEV₁ in asthmatic children with personal and microenvironmental exposure to airborne particulate matter. *Environ Health Perspect* 2004;112:932–941.
16. Pelkonen AS, Nikander K, Turpeinen M. Reproducibility of home spirometry in children with newly diagnosed asthma. *Pediatr Pulmonol* 2000;29:34–38.
17. Thiadens HA, De Bock GH, Van Houwelingen JC, Dekker FW, De Waal MW, Springer MP, Postma DS. Can peak expiratory flow measurements reliably identify the presence of airway obstruction and bronchodilator response as assessed by FEV₁ in primary care patients presenting with a persistent cough? *Thorax* 1999;54:1055–1060.
18. Giannini D, Paggiaro PL, Moscato G, Gherson G, Bacci E, Bancalari L, Dente FL, Di Franco A, Vagaggini B, Giuntini C. Comparison between peak expiratory flow and forced expiratory volume in one second (FEV₁) during bronchoconstriction induced by different stimuli. *J Asthma* 1997;34:105–111.
19. Hegewald MJ, Crapo RO, Jensen RL. Intraindividual peak flow variability. *Chest* 1995;107:156–161.
20. Vaughan TR, Weber RW, Tipton WR, Nelson HS. Comparison of PEF and FEV₁ in patients with varying degrees of airway obstruction. Effect of modest altitude. *Chest* 1989;95:558–562.